

### § 1310.03

- (8) Hydrochloric acid (including anhydrous hydrogen chloride) .....6545
- (9) Sulfuric acid .....6552
- (10) Methyl Isobutyl Ketone (MIBK) .....6715
- (11) Iodine .....6699

(c) The Administrator may add or delete a substance as a listed chemical by publishing a final rule in the FEDERAL REGISTER following a proposal which shall be published at least 30 days prior to the final rule.

(d) Any person may petition the Administrator to have any substance added or deleted from paragraphs (a) or (b) of this section.

(e) Any petition under this section shall contain the following information:

(1) The name and address of the petitioner;

(2) The name of the chemical to which the petition pertains;

(3) The name and address of the manufacturer(s) of the chemical (if known);

(4) A complete statement of the facts which the petitioner believes justifies the addition or deletion of the substance from paragraphs (a) or (b) of this section;

(5) The date of the petition.

(f) The Administrator may require the petitioner to submit such documents or written statements of fact relevant to the petition as he deems necessary in making a determination.

(g) Within a reasonable period of time after the receipt of the petition, the Administrator shall notify the petitioner of his decision and the reason therefor. The Administrator need not accept a petition if any of the requirements prescribed in paragraph (e) of this section or requested pursuant to paragraph (f) of this section are lacking or are not clearly set forth as to be readily understood. If the petitioner desires, he may amend and resubmit the petition to meet the requirements of paragraphs (e) and (f) of this section.

(h) If a petition is granted or the Administrator, upon his own motion, proposes to add or delete substances as listed chemicals as set forth in paragraph (c) of this section, he shall issue and publish in the FEDERAL REGISTER a proposal to add or delete a substance as a listed chemical. The Administrator shall permit any interested person to file written comments regarding the

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proposal within 30 days of the date of publication of his order in the FEDERAL REGISTER. The Administrator will consider any comments filed by interested persons and publish a final rule in accordance with his decision in the matter.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 48733, Sept. 26, 1991; 57 FR 43615, Sept. 22, 1992; 60 FR 19510, Apr. 19, 1995; 60 FR 32460, June 22, 1995; 62 FR 5917, Feb. 10, 1997; 65 FR 21647, Apr. 24, 2000; 65 FR 47316, Aug. 2, 2000; 66 FR 52675, Oct. 17, 2001]

#### § 1310.03 Persons required to keep records and file reports.

(a) Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction as specified by § 1310.04 and file reports as specified by § 1310.05. However, a non-regulated person who acquires listed chemicals for internal consumption or “end use” and becomes a regulated person by virtue of infrequent or rare distribution of a listed chemical from inventory, shall not be required to maintain receipt records of listed chemicals under this section.

(b) Each regulated person who manufactures a List I or List II chemical shall file reports regarding such manufacture as specified in Section 1310.05.

(c) Each regulated person who engages in a transaction with a nonregulated person or who engages in an export transaction that involves ephedrine, pseudoephedrine, phenylpropanolamine, or gamma-hydroxybutyric acid, including drug products containing these chemicals, and uses or attempts to use the Postal Service or any private or commercial carrier must file monthly reports of each such transaction as specified in § 1310.05 of this part.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 8277, Feb. 28, 1991; 61 FR 14023, Mar. 29, 1996; 67 FR 14861, Mar. 28, 2002; 68 FR 57804, Oct. 7, 2003; 70 FR 294, Jan. 4, 2005]

#### § 1310.04 Maintenance of records.

(a) Every record required to be kept subject to § 1310.03 for a List I chemical, a tableting machine, or an encapsulating machine shall be kept by the

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regulated person for 2 years after the date of the transaction.

(b) Every record required to be kept subject to Section 1310.03 for List II chemical shall be kept by the regulated person for two years after the date of the transaction.

(c) A record under this section shall be kept at the regulated person's place of business where the transaction occurred, except that records may be kept at a single, central location of the regulated person if the regulated person has notified the Administration of the intention to do so. Written notification must be submitted by registered or certified mail, return receipt requested, to the Special Agent in Charge of the DEA Divisional Office for the area in which the records are required to be kept.

(d) The records required to be kept under this section shall be readily retrievable and available for inspection and copying by authorized employees of the Administration under the provisions of 21 U.S.C. 880.

(e) The regulated person with more than one place of business where records are required to be kept shall devise a system to detect any party purchasing from several individual locations of the regulated person thereby seeking to avoid the application of the cumulative threshold or evading the requirements of the Act.

(f) For those listed chemicals for which thresholds have been established, the quantitative threshold or the cumulative amount for multiple transactions within a calendar month, to be utilized in determining whether a receipt, sale, importation or exportation is a regulated transaction is as follows:

(1) List I chemicals:

(i) Except as provided in paragraph (f)(1)(ii) of this section, the following thresholds have been established for List I chemicals.

| Chemical  | Threshold by base weight |
|---|--------------------------|
| (A) Anthranilic acid, its esters, and its salts                                   | 30 kilograms.            |
| (B) Benzyl cyanide  | 1 kilogram.              |
| (C) Ergonovine and its salts  | 10 grams.                |
| (D) Ergotamine and its salts  | 20 grams.                |
| (E) N-Acetylanthranilic acid, its esters, and its salts.                          | 40 kilograms.            |
| (F) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers. | 2.5 kilograms.           |

| Chemical   | Threshold by base weight              |
|--|---------------------------------------|
| (G) Phenylacetic acid, its esters, and its salts.  | 1 kilogram.                           |
| (H) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.                   | 2.5 kilograms.                        |
| (I) Piperidine and its salts   | 500 grams.                            |
| (J) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.                       | 1 kilogram.                           |
| (K) 3,4-Methylenedioxyphenyl-2-propanone   | 4 kilograms.                          |
| (L) Methylamine and its salts  | 1 kilogram.                           |
| (M) Ethylamine and its salts   | 1 kilogram.                           |
| (N) Propionic anhydride  | 1 gram.                               |
| (O) Isosafrole   | 4 kilograms.                          |
| (P) Safrole  | 4 kilograms.                          |
| (Q) Piperonal  | 4 kilograms.                          |
| (R) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers (N-Methylephedrine). | 1 kilogram.                           |
| (S) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers.               | 1 kilogram.                           |
| (T) Hydriodic Acid   | 1.7 kilograms (or 1 liter by volume). |
| (U) Benzaldehyde   | 4 kilograms.                          |
| (V) Nitroethane  | 2.5 kilograms.                        |

(ii) Notwithstanding the thresholds established in paragraphs (f)(1)(i) and (g) of this section, the following thresholds will apply for the following List I chemicals that are contained in drug products that are regulated pursuant to §1300.02(b)(28)(i)(D) of this chapter (thresholds for retail distributors and distributors required to report under §1310.03(c) of this part are for a single transaction; the cumulative threshold provision does not apply. All other distributions are subject to the cumulative threshold provision.):

| Chemical   | Threshold by weight                       |
|--|---|
| (A) Ephedrine, its salts, optical isomers, and salts of optical isomers as the sole therapeutically significant medicinal ingredient.                            | No threshold. All transactions regulated. |
| (B) Ephedrine, its salts, optical isomers, and salts of optical isomers in combination with therapeutically significant amounts of another medicinal ingredient: |   |
| (1) Distributions by retail distributors.  | 24 grams.                                 |
| (2) Distributions by persons required to report under § 1310.03(c) of this part.   | 24 grams.                                 |
| (3) All other domestic distributions (other than paragraphs (f)(1)(ii)(B) (1) and (2) of this section).  | 1 kilogram.                               |
| (4) Imports and Exports  | 1 kilogram                                |

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| Chemical  | Threshold by weight  | Chemical  | Threshold by weight  |
|---|--|---|--|
| (C) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers (other than ordinary over-the-counter products):<br>(1) Distributions by retail distributors. | 9 grams, and sold in package sizes of not more than 3 grams of pseudoephedrine base. | (E) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers (other than ordinary over-the-counter products):<br>(1) Distributions by retail distributors. | 9 grams, and sold in package sizes of not more than 3 grams of phenylpropanolamine base. |
| (2) Distributions by persons required to report under § 1310.03(c) of this part.  | 9 grams, and sold in package sizes of not more than 3 grams of pseudoephedrine base. | (2) Distributions by persons required to report under § 1310.03(c) of this part.  | 9 grams, and sold in package sizes of not more than 3 grams of phenylpropanolamine base. |
| (3) All other domestic distributions, (other than paragraphs (f)(1)(ii)(C) (1) and (2) of this section).  | 1 kilogram.  | (3) All other domestic distributions (other than paragraphs (f)(1)(ii)(E) (1) and (2) of this section).   | 2.5 kilograms.   |
| (4) Imports and Exports .....   | 1 kilogram.  | (4) Imports and Exports .....   | 2.5 kilograms.   |
| (D) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers (ordinary over-the-counter products):<br>(1) Distributions by retail distributors.            | Exempt.  | (F) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers (ordinary over-the-counter products):<br>(1) Distributions by retail distributors.            | Exempt.  |
| (2) Distributions by persons required to report under § 1310.03(c) of this part.  | 9 grams, and sold in package sizes of not more than 3 grams of pseudoephedrine base. | (2) Distributions by persons required to report under § 1310.03(c) of this part.  | 9 grams, and sold in package sizes of not more than 3 grams of phenylpropanolamine base. |
| (3) All other domestic distributions (other than paragraphs (f)(1)(ii)(D) (1) and (2) of this section).   | 1 kilogram.  | (3) All other domestic distributions (other than paragraphs (f)(1)(ii)(F) (1) and (2) of this section).   | 2.5 kilograms.   |
| (4) Imports and Exports .....   | 1 kilogram.  | (4) Imports and Exports .....   | 2.5 kilograms.   |

(2) List II Chemicals:  
(i) Imports and Exports

| Chemical                         | Threshold by volume | Threshold by weight |
|----------------------------------|---------------------|---------------------|
| (A) Acetic anhydride .....       | 250 gallons .....   | 1,023 kilograms.    |
| (B) Acetone .....                | 500 gallons .....   | 1,500 kilograms.    |
| (C) Benzyl chloride .....        | N/A .....           | 4 kilograms.        |
| (D) Ethyl ether .....            | 500 gallons .....   | 1,364 kilograms.    |
| (E) Potassium permanganate ..... | N/A .....           | 500 kilograms.      |
| (F) 2-Butanone (MEK) .....       | 500 gallons .....   | 1,455 kilograms.    |
| (G) Toluene .....                | 500 gallons .....   | 1,591 kilograms.    |

(ii) Domestic Sales

| Chemical                         | Threshold by volume | Threshold by weight |
|----------------------------------|---------------------|---------------------|
| (A) Acetic anhydride .....       | 250 gallons .....   | 1,023 kilograms.    |
| (B) Acetone .....                | 50 gallons .....    | 150 kilograms.      |
| (C) Benzyl chloride .....        | N/A .....           | 1 kilogram.         |
| (D) Ethyl ether .....            | 50 gallons .....    | 135.8 kilograms.    |
| (E) Potassium permanganate ..... | N/A .....           | 55 kilograms.       |
| (F) 2-Butanone (MEK) .....       | 50 gallons .....    | 145 kilograms.      |
| (G) Toluene .....                | 50 gallons .....    | 159 kilograms.      |
| (H) Iodine .....                 | N/A .....           | 0.4 kilograms.      |

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| Chemical                              | Threshold by volume | Threshold by weight |
|---------------------------------------|---------------------|---------------------|
| (I) Anhydrous Hydrogen chloride ..... | N/A .....           | 0.0 kilograms.      |

(iii) The cumulative threshold is not applicable to domestic sales of Acetone, 2-Butanone (MEK), and Toluene.

(iv) Exports, Transshipments and International Transactions to Designated Countries as Set Forth in §1310.08(b).

| Chemical   | Threshold by volume | Threshold by weight |
|--|---------------------|---------------------|
| (A) Hydrochloric acid<br>(1) Anhydrous<br>Hydrogen chloride. | 50 gallons<br>..... | 27 kilograms.       |
| (B) Sulfuric acid .....                                      | 50 gallons          |                     |

(v) Export and International Transactions to Designated Countries, and Importations for Transshipment or Transfer to Designated Countries

| Chemical                              | Threshold by volume | Threshold by weight |
|---------------------------------------|---------------------|---------------------|
| (A) Methyl Isobutyl<br>Ketone (MIBK). | 500 gallons .....   | 1523 kilograms.     |
| (B) Reserved.                         |                     |                     |

(g) For listed chemicals for which no thresholds have been established, the size of the transaction is not a factor in determining whether the transaction meets the definition of a regulated transaction as set forth in §1300.02(b)(28) of this chapter. All such transactions, regardless of size, are subject to recordkeeping and reporting requirements as set forth in this part and notification provisions as set forth in part 1313 of this chapter.

(1) Listed chemicals for which no thresholds have been established:

(i) Ephedrine, its salts, optical isomers and salts of optical isomers

(ii) Red phosphorus

(iii) White phosphorus (Other names: Yellow Phosphorus)

(iv) Hypophosphorous acid and its salts

(v) gamma-Butyrolactone (Other names include: GBL; Dihydro-2(3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone)

(2) [Reserved]

(h) The thresholds and conditions in paragraphs (f) and (g) of this section will apply to transactions involving regulated chemical mixtures. For purposes of determining whether the weight or volume of a chemical mixture meets or exceeds the applicable quantitative threshold, the following rules apply:

(1) For chemical mixtures containing List I chemicals or List II chemicals other than those in paragraph (h)(2) of this section, the threshold is determined by the weight of the listed chemical in the chemical mixture.

(2) For the List II chemicals acetone, ethyl ether, 2-butanone, toluene, and methyl isobutyl ketone, the threshold is determined by the weight of the entire chemical mixture.

(3) If two or more listed chemicals are present in a chemical mixture, and the quantity of any of these chemicals equals or exceeds the threshold applicable to that chemical, then the transaction is regulated.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 48733, Sept. 26, 1991; 57 FR 43615, Sept. 22, 1992; 59 FR 51367, Oct. 11, 1994; 60 FR 19510, Apr. 19, 1995; 60 FR 32460, June 22, 1995; 60 FR 42436, Aug. 16, 1995; 62 FR 5917, Feb. 10, 1997; 65 FR 47316, Aug. 2, 2000; 66 FR 52675, Oct. 17, 2001; 67 FR 14861, Mar. 28, 2002; 68 FR 11472, Mar. 11, 2003; 68 FR 23203, May 1, 2003; 68 FR 53292, Sept. 10, 2003; 68 FR 57804, Oct. 7, 2003; 69 FR 74970, Dec. 15, 2004]

**§ 1310.05 Reports.**

(a) Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, as follows:

(1) Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part.

(2) Any proposed regulated transaction with a person whose description or other identifying characteristic the